

From: Tran, Dang P CTR (US)
Sent: Tuesday, June 24, 2014 3:31 PM
Subject: RE: Banned supplements (UNCLASSIFIED)ALCON,

There have been many inquiries from all Army components on dietary supplements. I suggest every Active installation and USAR/ARNG command should provide prevention training to their personnel on the topic of Dietary Supplements.

In general, dietary supplements (DS) are considered food products which may not be required to registered and approved by FDA as for drugs, and their formulas are often changed rapidly to avoid the stringent regulatory requirements. Even FDA cannot keep up with the products until they are already marketed and caused problems, in many cases.

Usually, the DS products (by marketed product name) are not banned, but they may be illegally marketed for containing banned substances listed on the Controlled Substances Act (CSA) schedules (I to V). The burden is on the DS users to make sure they are not using a products containing illegal substances.

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*Use of DS or food/drink containing Hemp or Hemp oil by Soldiers is prohibited by AR 600-85 Para 4-2p.

The DoD or Army enforces any ban by FDA and does not in general maintain a list of banned DS products.

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Known banned substances which may/may not be listed on the substance schedules (see CSA schedules):

- 1) Ephedrine (Ephedra) products were banned by FDA action in 2004.
- 2) DMAA illegally formulated in DS products. Consumers should look for DMAA listed on the product label. It may also be listed as:
 - 1,3-DMAA
 - 1,3-Dimethylamylamine
 - 1,3-Dimethylpentylamine
 - 2-Amino-4-methylhexane
 - 2-Hexanamine
 - 4-Methyl-2-hexanamine
 - 4-Methyl-2-hexylamine
 - 4-methyl- (9CI)
 - Dimethylamylamine
 - Geranamine
 - Methylhexanamine
 - Methylhexanenamine

Some products also will list Pelargonium graveolens extract or Geranium extract, which may indicate that the product contains DMAA.

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Useful search tool on the FDA site for the latest information on a substance.

*DS containing DMAA was determined illegal by FDA since July 20013
<http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/ucm346576.htm>.

*11 Oct 2013, FDA advised consumers not to use the dietary supplement product labeled OxyElite Pro OxyElite Pro or VERSA-1, which are being investigated for possible link to acute hepatitis illnesses. In a warning letter¹ issued to USP Labs LLC of Dallas Texas on October 11, 2013, the FDA informed the company that the dietary supplements OxyElite Pro and VERSA-1 are deemed to be adulterated.
<http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm370849.htm>.

*FDA List of tainted/adulterated DS
http://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?filter=&sortColumn=1d&sd=tainted_supplements_cder&displayAll=true.

*FDA Safety Alerts & Advisories
<http://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/default.htm>.

*FDA Recalls, Market Withdrawal, and Safety Alerts
<http://www.fda.gov/Safety/Recalls/default.htm>

*FDA Q&A on Dietary Supplements
<http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm#responsible>

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GENERAL AWARENESS ABOUT DIETARY SUPPLEMENTS:

For their own health and safety, users of dietary supplements are encouraged to review the advisories:

- *Consult with health care providers and Registered Dietitians at local MTF.
- *Read the label to see if the product is safe.
- *The Food and Drug Administration (FDA) does not test or approve dietary supplements before they are marketed to the public.
- *Many products on the market are dangerous to user's health, and physical activity may increase the risk.

Useful information resources for dietary supplement users:

US Army Public Health Command's dietary supplement page
<http://phc.amedd.army.mil/TOPICS/HEALTHYLIVING/N/Pages/DietarySupplements.aspx>

Consortium for Health and Military Performance
<http://www.usuhs.mil/mem/chnutrition.html>

Looking for the Edge- Dietary Supplements
<http://www.usuhs.mil/mem/pdf/DietarySupplementsGuide.pdf>

Force Health Protection: Nutrition and Exercise Resource Manual
http://www.usuhs.edu/mem/hpl/Navy_Guides.pdf

Peak Performance Through Nutrition and Exercise Ergogenics Pamphlet
<http://www.usuhs.edu/mem/hpl/ergopam.pdf>

Dietary Supplements and Military Divers: A Synopsis for Undersea Medical Officers

<http://www.usuhs.edu/mem/hpl/DietarySupplementUMO.pdf>

FDA Information for Consumers on Dietary Supplements

<http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/default.htm>

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DEA CONTROLLED SUBSTANCE LISTS (check the date of the version at the bottom)
Alphabetical Order

http://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf

DEA Drug Code Number

http://www.deadiversion.usdoj.gov/schedules/orangebook/d_cs_drugcode.pdf

CSA Schedules

http://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf

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CONTROLLED SUBSTANCES per 21 Code of Federal Regulation (lists updated as of date of the web page)

21 CFR Section 1308.11 Schedule I.

http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_11.htm

Section 1308.12 Schedule II

http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_12.htm

Section 1308.13 Schedule III

http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_13.htm

Section 1308.14 Schedule IV

http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_14.htm

Section 1308.15 Schedule V

http://www.deadiversion.usdoj.gov/21cfr/cfr/1308/1308_15.htm

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*More information on DS and illegal substances may be found at the ACSAP AKO Pages:

<https://www.us.army.mil/suite/page/594495>

<https://www.us.army.mil/suite/page/680607>

*Training on nutrition and DS information sources

<http://www.usuhs.mil/mem/chnutrition.html>

<https://www.us.army.mil/suite/doc/39107808>

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